AWARD NUMBER: W81XWH-14-2-0019

TITLE: Hearing Preservation Electrodes in Veterans and Military Servicemembers With Noise-Induced Hearing Loss

PRINCIPAL INVESTIGATOR: Dr. Marlan Hansen

CONTRACTING ORGANIZATION: IOWA CITY VA RESEARCH FOUNDATION
IOWA CITY, IA 52246-0000

REPORT DATE: July 2016

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

# REPORT DOCUMENTATION PAGE

*Form Approved*
*OMB No. 0704-0188*



| 1. REPORT DATE | 2. REPORT TYPE | 3. DATES COVERED |
|---|---|---|
| July 2016 | Annual | 15 Jun 2015 - 14 Jun 2016 |

**4. TITLE AND SUBTITLE**

Hearing Preservation Electrodes in Veterans and Military Servicemembers With Noise-Induced Hearing Loss

**5a. CONTRACT NUMBER**

**5b. GRANT NUMBER**
W81XWH-14-2-0019

**5c. PROGRAM ELEMENT NUMBER**

**6. AUTHOR(S)**

Marlan Hansen, MD

E-Mail: marlan-hansen@uiowa.edu

**5d. PROJECT NUMBER**

**5e. TASK NUMBER**

**5f. WORK UNIT NUMBER**

**7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)**

University of Iowa
Department of Otolaryngology
200 Hawkins Drive
Iowa City, IA 52242

**8. PERFORMING ORGANIZATION REPORT NUMBER**

**9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)**

U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

**10. SPONSOR/MONITOR'S ACRONYM(S)**

**11. SPONSOR/MONITOR'S REPORT NUMBER(S)**

**12. DISTRIBUTION / AVAILABILITY STATEMENT**

Approved for Public Release; Distribution Unlimited

**13. SUPPLEMENTARY NOTES**

**14. ABSTRACT**

There is a very real need to provide rehabilitative options for veterans and service members with severe noise-induced hearing loss (NIHL). Recent studies indicate that hearing preservation electrodes provide much better auditory rehabilitation compared with hearing aids or traditional length cochlear implants for patients with severe-to-profound high-frequency hearing loss and useable low-frequency hearing. The effectiveness of the hybrid approach for rehabilitation of NIHL has yet to be established. The purpose of this study is to document benefit of the hybrid cochlear implant in this population. This report documents progress during year 1 of the funding period. The initial portion of the year focused on obtaining Iowa/VA IRB and DoD HRPO approval. Following that time period we have focused on recruitment.

**15. SUBJECT TERMS**

IRB, VA IRB, DoD HRPO approval

| 16. SECURITY CLASSIFICATION OF: | | | 17. LIMITATION OF ABSTRACT | 18. NUMBER OF PAGES | 19a. NAME OF RESPONSIBLE PERSON |
|---|---|---|---|---|---|
| a. REPORT | b. ABSTRACT | c. THIS PAGE | | | USAMRMC |
| Unclassified | Unclassified | Unclassified | Unclassified | | 19b. TELEPHONE NUMBER *(include area code)* |

## Table of Contents

**Page**

**1. INTRODUCTION:** There is a very real need to provide rehabilitative options for veterans and service members with severe noise-induced hearing loss (NIHL). Recent studies indicate that hearing preservation electrodes provide much better auditory rehabilitation compared with hearing aids or traditional length cochlear implants for patients with severe-to-profound high-frequency hearing loss and useable low-frequency hearing. The effectiveness of the hybrid approach for rehabilitation of NIHL has yet to be established. The purpose of this study is to document benefit of the hybrid cochlear implant in this population

**2. KEYWORDS:** Hybrid cochlear implant, hearing preservation, noise-induced hearing loss

**3. ACCOMPLISHMENTS:**

**What were the major goals of the project?**

**A.** Recruitment and implantation of the Hybrid device.

**B.** Collect pre-and post-operative hearing threshold data.

**C.** Collect pre- and post-operative speech perception data.

**D.** Collect music appraisal and pitch data.

**E.** Administer training programs and questionnaires.

**What was accomplished under these goals?**

**A.** Recruitment for newly implanted subjects under this study has moved slowly. In order to increase our enrollment, we have received IRB and DoD HRPO approval to remove the upper age restriction for inclusion. As a result, we have enrolled and implanted 6 newly implanted subjects with the Hybrid L24 cochlear implant at the Iowa City VA Hospital. One subject subsequently dropped out of the study following surgery as he decided that he did not want to participate in a research study. Furthermore, one subject enrolled into our study at his six-month post-operative visit. Furthermore, we also received IRB and DoD HRPO approval to follow other Hybrid subjects who were previously implanted at the University of Iowa that are veterans of the military. An additional seven hybrid subjects are being followed under this study as military veterans who were

previously implanted at the University of Iowa. What is especially interesting about this newly included population is that we have longitudinal data on these individuals which demonstrates that is device can be a long-term solution to hearing impairment. Table 1 shows the time post-implantation for each subject in months, the hybrid cochlear implant type, and whether they were implanted at the University of Iowa (UI) or at the Iowa City VA (VA). Table 2 gives a description of the Hybrid Cochlear Implant device type.

**Table 1. Demographic subject information. IA (Initial Activation); UI (University of Iowa); VA (Iowa City VA)**

| Group | Subject | Months Post-implantation | Hybrid Implant Type | Implant Location |
|---|---|---|---|---|
| Previously Implanted | A-01 | 48 | L24 | UI |
| | A-10 | 24 | L24 | UI |
| | S12-S2 | 84 | S12 | UI |
| | S8-S2 | 156 | S8 | UI |
| | S8-S17 | 84 | S8 | UI |
| | IS5 | 48 | L24 | UI |
| | S8-03 | 144 | S8 | UI |
| Newly Implanted | DoD-01-L24 | IA | L24 | VA |
| | DoD-02-L24 | 6 | L24 | VA |
| | DoD-03-L24 | Withdrew from study | | |
| | DOD-04-L24 | IA | L24 | VA |
| | DOD-05-L24 | IA | L24 | VA |
| | DOD-06-L24 | IA | L24 | VA |

**Table 2. Hybrid Cochlear Implant description**

| Name | Number of Electrodes | Length (mm) |
|---|---|---|
| S8 | 6 | 10 |
| L24 | 24 | 16 |
| S12 | 10 | 10 |
| S12 RW | 10 | 12 |

**B.** Figure 1 shows the unaided thresholds at the subjects' most recent appointment. All of the subjects (with the exception of S12-S2 and S8-03) have functional post-operative preserved residual hearing. We describe functional hearing as hearing that can be aided with an acoustic component in the low-frequency region. Thus, they are listening with both

acoustic and electric information in the same ear. Four of the newly implanted subjects have thresholds tested at their initial activation as they are newly implanted (See Table 1). Only two of the subjects have a hearing loss that falls below the functional hearing range (approximately >85 dB HL). The two subjects are denoted in Figure 1 with an asterisk by their subject name (S12-S2 and S8-03). These two subjects are now using the cochlear implant on one ear and a hearing aid in the opposite ear (bimodal hearing).

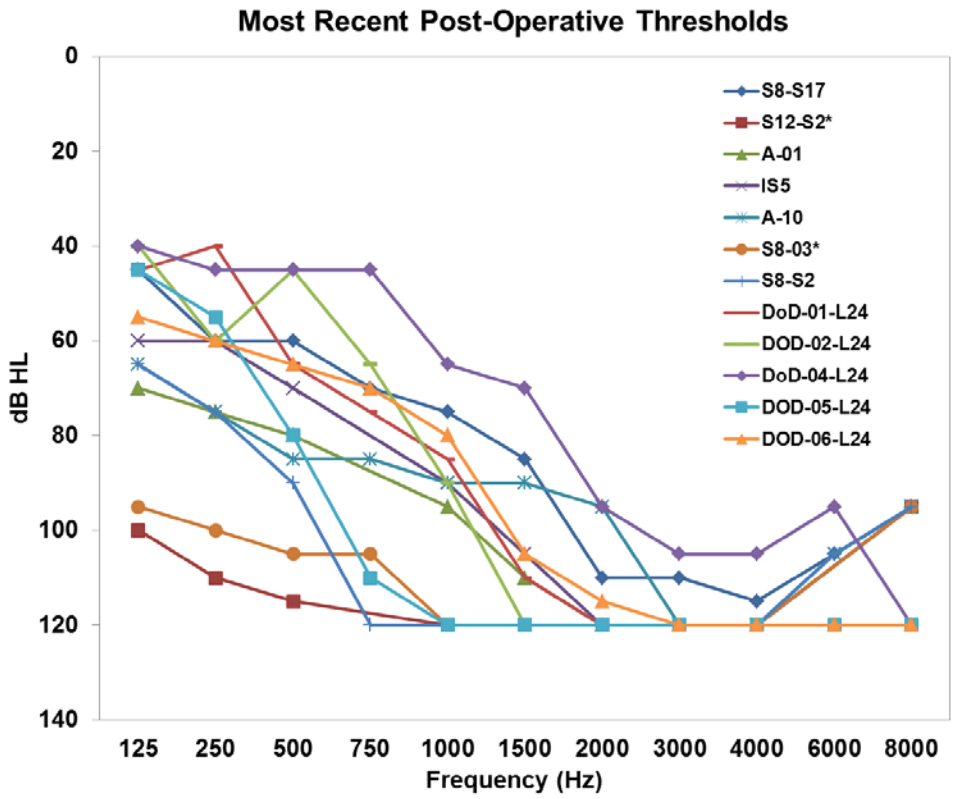


Figure 1. Individual post-operative unaided hearing thresholds in the implanted ear.

**C.** We have collected pre-operative data on all of our newly implanted subjects, except for the subject who enrolled at his 6 month data point. The data includes speech perception, localization, and music data. We are also collecting quality of life and functional questionnaire data.

In Figure 2, we show post-operative speech understanding in the combined condition (bilateral hearing aids and a CI) in Panel A and the Hybrid condition (ipsilateral Hearing aid and CI) in Panel B using the CNC word scores for the individuals in Table 1. The two

individuals who lost all of their hearing post-operatively in the implanted ear (denoted with an asterisk next to their name) are shown in the bimodal listening condition (Contralateral hearing aid and CI) in Panel A and in the CI only condition in Panel B. Those with only initial activation information were not tested on speech perception post-operatively as of yet. We will collect speech perception data on them post-operatively at 6, 12, and annually postoperatively, as per the protocol.

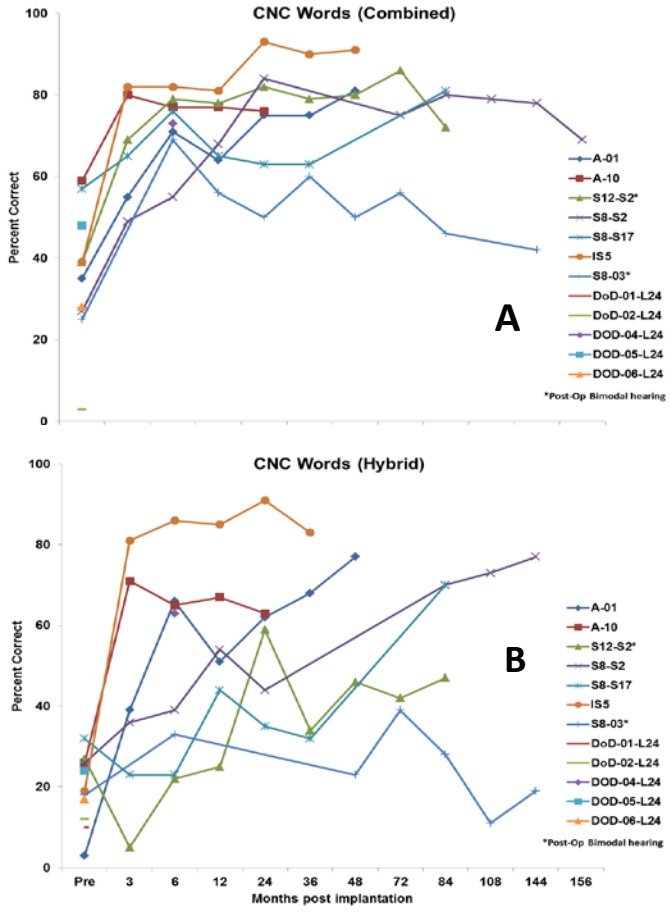


Figure 2. Individual CNC word scores over time. Panel A shows the scores in the Combined listening condition and Panel B shows the scores in the Hybrid listening condition.

**D.** Music perception and enjoyment data were collected from 5 subjects implanted as part of the DoD protocol during this reporting period. For these 5 subjects, we have music perception and enjoyment preoperative data for 4 and postoperative data for 1. One of the most salient features of music perception, which is also problematic for most conventional

cochlear implant users is pitch (perceptual correlate of frequency), or how high or low a note is. The pre-operative scores on pitch perception averaged 7.25 semitones (range of 1-17 semitones). The postoperative score for the one DoD subject who has completed postoperative testing was 4 semitones (in hybrid and CI only conditions). Melodies are made up of sequences of pitches that move higher, lower, or stay the same. The pattern of sequential pitches is sometimes referred to as melodic contour. Evaluation of melodic contour also occurred pre- and postoperatively for the DoD subjects. The average preoperative score on melodic contour for this group was 68.75% correct (range of 57.5 to 83.75% correct). The postoperative score for the one DoD subject was 73.75% correct.

In addition to gathering data for these five new CI recipients, we have also examined the longer-term results of 7 individuals with military service who were implanted with Hybrid CIs prior to the implementation of the DoD recruitment protocol. This group includes users of the S8, S12, and L24 internal arrays. The mean of pre-operative pitch scores available for this group (n=3) was 14. 67 (range of 7-22 semitones). The average post-operative scores for this group was 9 semitones (range of 2-19 semitones) in the hybrid condition and 12 semitones (range of 2-24) in the CI only condition. On melody contour testing postoperatively, this group ranged in accuracy from 53.75 to 92.5% correct.

**E.** One of the primary reasons that people listen to music is because music is associated with mood and emotion. Consider, for example, how music is used as background for films to support the emotional message of a film (e.g., scary music in horror films, up-beat happy music for comedies, etc.). Prior research indicates that recipients of conventional long electrode CIs are significantly less accurate than normal hearing listeners in recognizing the emotional content of music. We tested the DoD subjects (who use hybrid devices) on recognition of emotion in music. The average preoperative score for the 5 DoD subjects was 55% correct. The DoD subject who has been testing post-operatively achieved a score of 86.67% correct. Two of the previously implanted recipients (1 S8, 1 L24) were tested post-operatively on this test during this funding period. [NOTE: This test was recently integrated into our protocol, and thus, we do not have pre-operative scores for this group.] They scored 33.33% and 73.33% correct, respectively.

We did not collect data on the Real World Melody Recognition, Modified Melodies Test, or the Iowa Test Appraisal of Sound Quality, as those measures evaluate perception but do not address the goals of assisting the CI recipients in returning to their everyday social and musical interactions. The implemented measures, instead evaluate how well they are able to utilize the cues available to connect with their family and social circles.

**F.** During this funding period, we validated a newly developed questionnaires specifically designed to determine musical experiences and preferences of persons with military experience. This was administered to the 5 DoD subjects. Because this questionnaire gathers information on musical preferences, as well as musical selections that may be associated with traumatic experiences during combat, this information can assist in the selection of appropriate stimuli items for training program which are to be implemented as part of this project. All subjects have completed the questionnaire without issue, with 2 commenting on their appreciation that the music team is attempting to avoid music that "triggers" negative memories in our training program.

**G.** Our postoperative DoD subject also completed the online training, which focused on attention to lyrics within background music of varying complexities. We did observe improvement from the first to the last lesson and the subject expressed appreciation for the training. Additionally, the subject shared that his difficulty in lyric perception was one reason he tended to listen to music without lyrics and with more simply melody contour.

**H.** The Hybrid S12RW device is approved for 10 subjects under a Cochlear Americas Sponsored Investigational Device Exemption (IDE). The University of Iowa is the single-site implanting these devices. We will enroll subjects into this study if they are veterans. Once the single-site IDE is completed, the study will open up to a larger multi-center study.

**What opportunities for training and professional development has the project provided?**

This project was not intended to provide training and professional development opportunities. However, Dr. Dunn has spoken on several occasions to Nancy Cambron, who is the Chair of the VHA Cochlear Implant Advisory Board, and Maureen Wargo, who is a supervisory audiologist within the VA Pittsburgh Healthcare System. Both have had

questions regarding use of the hybrid cochlear implant in veterans. Dr. Dunn also traveled to several VA attended meetings to discuss device outcomes and expectations.

**How were the results disseminated to communities of interest?**

Nothing to report

**What do you plan to do during the next reporting period to accomplish the goals?**

During the next year, we plan to continue to obtain post-operative data on those implanted and also recruit new individuals. We will begin training on the patients at 6 months post-implantation.

**4. IMPACT:**

**What was the impact on the development of the principal discipline(s) of the project?**

Nothing to report

**What was the impact on other disciplines?**

Nothing to report

**What was the impact on technology transfer?**

Nothing to report

**What was the impact on society beyond science and technology?**

Nothing to report

**5. CHANGES/PROBLEMS:**

**Changes in approach and reasons for change**

Nothing to report

**Actual or anticipated problems or delays and actions or plans to resolve them**

As mentioned previously, recruitment has been slow for this project. We continue to initiate conversations with various individuals within the VA and military branches.

**Changes that had a significant impact on expenditures**

Nothing to report

**Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents**

Nothing to report

**Significant changes in use or care of human subjects**

Nothing to report

**Significant changes in use or care of vertebrate animals.**

Not applicable

**Significant changes in use of biohazards and/or select agents**

Not applicable

## 6. PRODUCTS:

Nothing to report

## 7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

**What individuals have worked on the project?**

(1) Name: Marlan Hansen
Project Role: PI
Nearest person month worked: 1
Contribution to Project: Assisted in IRB/HRPO submission and recruitment.

(2) Name: Bruce Gantz
Project Role: Co-PI
Nearest person month worked: 1
Contribution to Project: Assisted in IRB/HRPO submission and recruitment.

(3) Name: Camille Dunn
Project Role: Investigator
Nearest person month worked: 3
Contribution to Project: Assisted in IRB/HRPO application; discussed project with VA staff; developed CRF forms; developed marketing forms for recruitment.

(4) Name: Diane Burke
Project Role: Study Coordinator
Nearest person month worked: 3
Contribution to Project: Prepared the IRB/HRPO submission; assisted in the development of marketing forms for recruitment.

(5) Name: Kate Gfeller

Project Role: Investigator
Nearest person month worked: 1
Contribution to Project: Began development on the training programs

(6) Name: Virginia Driscoll
Project Role: Research Assistant
Nearest person month worked: 1
Contribution to Project: Began development on the training programs

**Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?**

Nothing to report

**What other organizations were involved as partners?**

Nothing to report

**QUAD CHARTS:** Attached.

**8. SPECIAL REPORTING REQUIREMENTS:**

Nothing to report

**9. APPENDICES:**

Nothing to report

# Hearing Preservation Electrodes in Veterans and Military Service Members with Noise-Induced Hearing Loss

**Award Number: W81XWH-14-2-0019 Log Number: DM130040**

**PI:** Marlan Hansen, MD. **CO-PI:** Bruce Gantz, MD **Org:** Clinical and Rehabilitative Medicine Research Program **Award Amount:** $2 mil

**Problem and Military Relevance**

- High percentage of veterans and military service members suffer Noise-induced hearing loss (NIHL).
- HL gives rise to substantial fiscal burden for the VA
- NIHL results in significant communicative, social and economic burden to veterans and service members

**Study Aim(s)**

- Evaluate the benefit of different lengths of hybrid CIs on veterans and service members with HF NIHL
- Evaluate the impact of hearing loss rehabilitation with short electrode CIs on quality of life.

**Approach**

- Veterans and military service members with HF NIHL will receive a L24 or S12 short electrode
- Benefit will be evaluated by comparing speech perception, music recognition, localization, and quality of life prior to implantation and over the first year following implantation.
- Benefit will be assessed as a function of device length.

**Goals/Milestones**

**CY14 Goal** – Design protocol, FDA IDE, and test measures
✓ Design protocol and regulatory guidelines
✓ Begin recruitment of subjects
✓ IRB and HRPO approval

**CY15 Goals** – Recruitment and data collection
☐ Continue subject recruitment
☐ Collect pre-operative and post-operative data on subjects

**CY16 Goal** – Recruitment and data collection
☐ Finalize subject recruitment
☐ Collect pre-operative and post-operative data on subjects

**CY17 Goal** – Data collection, data analysis, dissemination
☐ Finish data collection
☐ Analyze data and prepare for dissemination of results

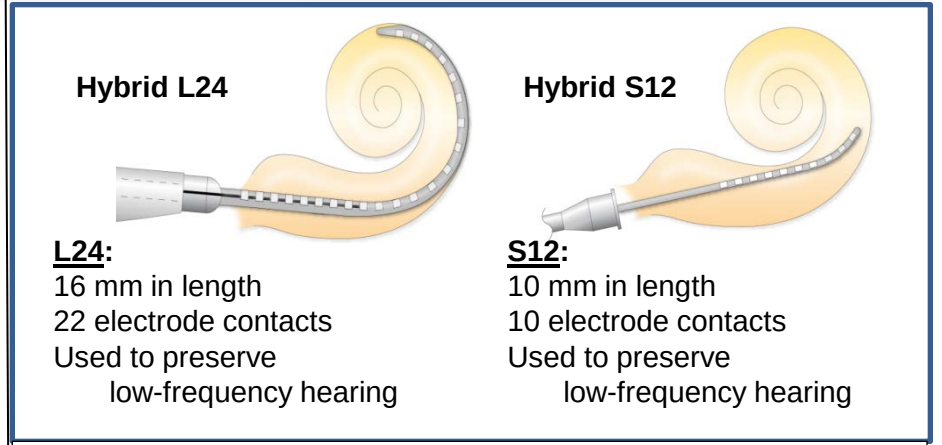


Figure 1. Schematic of Hybrid electrodes within the cochlea. The L24 (left) has 22 electrode contacts and is implanted into the cochlea 16 mm . The S12 (right) has 10 electrode contacts and is implanted into the cochlea 10 mm. Both electrodes are used to preserve low-frequency acoustic hearing.

**Timeline and Cost**

| Activities CY | 14 | 15 | 16 | 17 |
|---|---|---|---|---|
| Prepare protocol and test measures, submit FDA IDE | | | | |
| Recruitment of subjects | | | | |
| Pre- and Post- Op data collection | | | | |
| Data analysis and dissemination of results | | | | |
| **Estimated Budget ($K)** | **$500** | **$500** | **$500** | **$500** |

**Updated: Annual**